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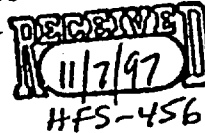
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November 4, 1997

James T. Tanner, Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration (HFS-451)
200 C Street, S.W.
Washington, D.C. 20204

Re: Evolve

Dear Dr. Tanner:

On December 24, 1996 Nutragenics submitted a notification pursuant to Section 403(r)(6) of the Act for its Evolve product with the dietary ingredient Clearesterol (a tocotrienol complex form of Vitamin E derived from rice bran). The notification contained 3 statements of nutritional support, including the claim "helps lower cholesterol".

On January 29, 1997, the company received a courtesy letter from you stating in pertinent part that "a product that claims to lower cholesterol, but is not used in the context of dietary management, is a drug within the meaning of Section 201(g)(1)(B) of the act and is subject to regulation under the drug provisions of the act."

On February 24, 1997, this firm wrote you on behalf of Nutragenics, which is now known as Bionutrics Health Products, Inc., that we would be working with the client to revise materials in accordance with your letter.

Please be advised that the company includes the following claim about dietary management in all labeling that the product helps lower cholesterol when taken as part of or in conjunction

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with "a low fat, low cholesterol diet and exercise." A new product label with this claim is currently being printed.

Thank you for your kind attention.

Sincerely yours,

BASS & ULLMAN, P.C.


Steven Shapiro

SS:ng

cc: Bionutrics Health Products, Inc.

CHAMBERLAIN